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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,815	02/20/2004	Bernard Charles Sherman	2051-59	3945

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EXAMINER	
AHMED, HASAN SYED	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/781,815	SHERMAN, BERNARD CHARLES	
	Examiner	Art Unit	
	Hasan S. Ahmed	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2/20/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the application and IDS filed on 20 February 2004.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

The use of the trademark CROSSCARMELLOSE SODIUM has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Specifically, claims 1 and 5-10 recite tablet disintegration times. However, no explanation or examples are given in the specification as to how these disintegration times are attained. Example 2 of the specification merely recites that "[t]he amount of disintegrant used was sufficient to cause the disintegration time of the tablets to be under 2 minutes." *See* pg. 4, lines 20-21 of the specification. No amounts, weights, percentages, or ratios of disintegrant were disclosed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-5, 7 and 9 recite the limitation "tablet." There is insufficient antecedent basis for this limitation in the claim. Based on the antecedent basis for these claims, the limitation should read "pharmaceutical tablet." Appropriate correction is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heacock, et. al. (U.S. 2004/0048931 A1) in view of Corvari, et. al. (U.S. 2003/0022940 A1).

Heacock, et. al. teach modafinil tablet formulations at various particle sizes (*see* paragraphs 0006, 0059, fig. 1).

The disclosed formulations teach up to 60% of modafinil particles larger than 200μm (*see* paragraphs 0074 and 0080, examples 6, 11, 16, 21, 26, 31, 36, 38 and 41).

Heacock, et. al. explain that "...by properly controlling the distribution and quantity of small particles, large particles, and very large particles (of modafinil) in the blend, dissolution and absorption post-ingestion of the pharmaceutical composition can be optimized, thereby providing a composition that is effective to alter the somnolent state of a subject." *See* paragraph 0006. "Small particles" are defined as smaller than or equal to about 200μm; "large particles" are defined as larger than 220μm in diameter; "very large particles" are defined as larger than 440μm.

Heacock, et. al. therefore disclose a modafinil tablet formulation comprising more than 50% of the modafinil particles having a diameter of more than 200μm and less than 5% of modafinil particles having a diameter of more than 800μm. Motivation to make this formulation, as disclosed by Heacock, et. al. comes from the desire to optimize dissolution and absorption properties in order to effectively alter the somnolent state of a subject.

The Heacock, et. al. reference differs from the instant case only in that it does not disclose a disintegration time of less than 20 minutes.

Corvari, et. al. teach compositions of modafinil that include modafinil and one or more diluents, disintegrants, binders and lubricants (paragraph 0001).

The disclosed compositions are comprised of, *inter alia*, 100 mg or 200 mg of modafinil per tablet (paragraph 0030); various disintegrants, *inter alia*, CROSSCARMELLOSE SODIUM (paragraph 0023); various binders and fillers, inter

alia, microcrystalline cellulose (paragraph 0024). The final blended mixture is compressed into a tablet form (paragraph 0044).

The Corvari, et. al. reference does not particularly address disintegration times. However, applicant's tablet is the same as the prior art. It uses the same the same ingredients and the same tableting process. Thus, absent a showing of unexpected results by applicant' s disintegration times, one of ordinary skill in the art would expect the same disintegration times as disclosed in the prior art.

Corvari, et. al. explain that the disintegration rate and other properties of the disclosed tablet are beneficial because they provides properties similar to PROVIGIL without inclusion of magnesium silicate or talc (paragraph 0006). This reduces time and expense of manufacture (paragraph 0008).

A person having ordinary skill in the art at the time of the invention would therefore find motivation to produce tablets comprising more than 5% of the modafinil particles with a diameter of more than 200μm and less than 5% of modafinil particles with a diameter of more than 800μm and disintegration times of less than 20 minutes, as taught by Heacock, et. al. in view of Corvari, et. al. Motivation would come from more effective alteration of the somnolent state of a subject, as taught by Heacock, et. al. and more cost effective manufacture, as taught by Corvari, et. al.

Those of ordinary skill in the art would expect similar properties from the instant composition, given the teachings of Heacock, et. al. in view of Corvari, et. al. Thus, the instant composition would have been obvious given the teachings of Heacock, et. al. in view of Corvari, et. al.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SUPERVISORY PATENT EXAMINER
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